REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated May 27, 2004 (the "Office Action"). As further explained below, Claims 1-4, 7, 9, 11, 12, 14 and 25-46 are pending in the present application. Claims 9, 11, 12, 14, 25-27 and 31-46 stand withdrawn from consideration. Claims 1-4, 7 and 28-30 are presently under consideration and Claims 1-4, 7 and 28-30 stand rejected. The issues presented in the Office Action are addressed below.

I. Election/Restriction Requirement

Applicants appreciate the Examiner's reconsideration of the restriction of the claims as presented in the Office Action dated March 19, 2004 and the further acknowledgment of Applicants' election with traverse of Group I (Claims 1-4, 7 and 28-30). In view of the Examiner's comments provided in the current Office Action, Applicants acknowledge that, as noted above, Claims 1-3, 7 and 28-30 are presently under consideration.

Applicants further appreciate the indication that where a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. §821.04. Accordingly, Applicants respectfully request rejoinder of withdrawn process claims dependent from product claims determined to be allowable.

II. Claim Rejections Under 35 U.S.C. §112

A. Claims 1-4, 7 and 28-30

Claims 1-4, 7 and 28-30 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. *See* Office Action, page 4. In particular, the Office Action states that "a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of any nucleic acid having at least 75% homology to SEQ ID NO:1 and 'essentially the

same biological properties as the disclosed latency promoter', or any naturally occurring allelic variant of the disclosed nucleic acid." Office Action, page 7. Applicants respectfully disagree with these assertions.

Applicants respectfully submit that it is not necessary that the present application exhaustively describe all nucleotide sequences having the recited sequence homology to the nucleic acid sequence as set forth in SEQ ID NO:1 and "'essentially the same biological properties as the disclosed latency promoter,' or any naturally occurring allelic variant of the disclosed nucleic acid," as alleged in the Office Action as noted above. "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). Thus, Applicants respectfully submit that Claims 1-4, 7 and 28-30 comply with the written description requirement.

Nonetheless, Applicants have amended Claims 1, 7 and 28 to recite "at least 95% homology with SEQ ID NO:1 and is active as a latency promoter." This recitation is supported by the application at page 9, lines 9-13. Applicants respectfully submit that it is not necessary or feasible to list all possible sequences having at least 95% sequence homology to the nucleic acid sequence as set forth in SEQ ID NO:1. Moreover, methods of determining sequence homology are well-known and readily available in the art. One skilled in the art would be able to readily envision a genus of nucleotide sequences having the recited level of sequence homology to the nucleic acid sequence as set forth in SEQ ID NO:1.

Accordingly, Applicants respectfully submit that Claims 1-4, 7 and 28-30 are supported by the specification as filed and respectfully request that the rejection under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement be withdrawn.

B. Claims 1-3, 4, 7 and 28-30

Claims 1-3, 4, 7 and 28-30 stand rejected under 35 U.S.C. §112, first paragraph as lacking enablement. *See* Office Action, page 7. In particular, the Office Action states that the specification "does not reasonably provide enablement for the broad scope of any nucleic acid encoding a latency promoter and which has at least 75% homology with SEQ ID NO:1." Office Action, page 7. Applicants respectfully disagree with this assertion.

Applicants concur that "[t]here are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue.'" as stated in the Office Action on pages 7-8. Applicants respectfully submit, however, that the specification provides substantial guidance as to how to identify an isolated nucleic acid which encodes a latency promoter, comprising a nucleic acid selected from the group consisting of: (a) the nucleic acid sequence as set forth in SEQ ID NO:1; and (b) a nucleic acid sequence which has a sequence homology with SEQ ID NO:1 as recited in the instant claims.

Applicants respectfully submit that one reasonably skilled in the art is apprised of methods and conditions that permit determination of nucleic acids that encode the promoter of the present invention and hybridize to the nucleic acid sequence of SEQ ID NO:1, particularly where the specification refers to *Molecular Cloning, A Laboratory Manual.* Cold Spring Harbor Laboratory (J. Sambrook et al. 2d Ed. 1989), which outlines well-known techniques used for carrying out molecular cloning protocols. *See* Present Application, page 9, lines 8-9. The specification also provides further guidance for carrying out such methods at page 8, line 29 through page 9, line 13.

However, as noted above, Applicants have amended Claims 1, 7 and 28 to recite "at least 95% homology with SEQ ID NO:1 and is active as a latency promoter" in order to recite a genus of molecules that share a close structural and functional relationship. Thus, Applicants respectfully submit that one skilled in the art relevant to the present invention would be able to practice the presently-claimed invention without "undue" experimentation.

Accordingly, Applicants respectfully submit that 1-3, 4, 7 and 28-30 are enabled under 35 U.S.C. §112, first paragraph and respectfully request that the rejection of these claims be withdrawn.

C. Claims 2 and 28

Claims 2 and 28 stand rejected under 25 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *See* Office Action, page 10. More specifically, the Office Action states that "[i]t would seem more likely that Applicants intend to capture molecules that are complementary to likely SEQ ID NO:1; in which case, reciting that the nucleic acid is homologous to SEQ ID NO:1 is improper. Clarification is requested." Office Action, page 11.

In view of the Examiner's request, Applicants have amended Claims 2 and 28 to recite that the nucleic acid sequence "is complementary to SEQ ID NO:1."

Accordingly, Applicants respectfully submit that Claims 2 and 28 are not indefinite under 35 U.S.C. § 112, second paragraph, and respectfully request that the rejection of these claims be withdrawn.

III. Claim Rejections Under 35 U.S.C. §102

Claims 1-3, 4, 7 and 28-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Nicholas et al. Virol. **188**: 296-310 (1992) ("Nicholas et al.") as evidenced by Entrez Nucleotide Database Accession No. M86409. More specifically, the Office Action states that "Nicholas et al. discloses a composition comprising isolated nucleic acid fragments of the HVS L-DNA in plasmid vectors . . . . Sequence obtained from this nucleic acid composition is disclosed as Accession No. M86409, which is 100% complementary to the instant SEQ ID NO:1 and demonstrates that the composition, which comprises double stranded DNA, also comprises the nucleic acid set forth in the instant application as SEQ ID NO:1." Office Action, pages 11-12. The Office Action further states that Claims 3, 4, 29 and 30 further limit the latency promoter of the nucleic acid to being encoded by a nucleic acid sequence of a certain specified length. This limitation is inherent to the nucleic acid of Nicholas et al. because the promoter sequence disclosed thereby is the same as the promoter sequence claimed. . . . . Therefore, the nucleic acid and

recombinant DNA of Nicholas et al. also anticipates claims 3, 4, 29 and 30." Office Action, page 12. Applicants respectfully disagree with this assertion.

Applicants note that "[a]nticipation under 35 U.S.C. §102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000) (*relying on Electro Med. Sys. S.A. v. Cooper Life Scis.,* 32 USPQ2d 1017, 1019 (Fed Cir. 1994). Applicants respectfully submit that Nicholas et al. describes a 43,658 base pair contiguous nucleotide sequence of the right terminal region of the HVS L-DNA. It is **complementary** to SEQ ID NO:1, therefore it does not disclose the **specific** nucleic acid sequence of SEQ ID NO:1. Nicholas et al. describes a reverse sequence of an intervening portion (designated *ECLF*1 gene) between the *ECLF*2 and *ECLF*3 genes. Accordingly, SEQ ID NO:1 is not disclosed with any specificity. One of ordinary skill in the art would not appreciate or recognize the claimed latency promoter sequence based on the raw sequence data of Nicholas et al. Moreover, Nicholas et al. assigns no utility to this region and further states that there is no direct evidence for expression of either the *ECLF*2 and *ECLF*3 gene products.

The Court of Claims of Patent Appeals has stated that the prior art must provide a "guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made." *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118 (CCPA 1967). Such direction or guidance with respect to the presently claimed invention is simply not to be found in Nicholas et al. From the perspective of one skilled in the art at the time of invention, working without knowledge of the present specification, Nicholas et al. would not provide an adequate written disclosure of the present invention so as to put the skilled worker in possession of the claimed invention. Consequently, Nicholas et al. does not teach an isolated nucleic acid which encodes a latency promoter, comprising a nucleic acid selected from the group consisting of: (a) the nucleic acid sequence as set forth in SEQ ID NO:1; and (b) a nucleic acid sequence which has at least 95% homology with SEQ ID NO:1 as recited in claim 1.

Turning to Claims 3, 4, 29 and 30, as noted above, the Office Action asserts that the recitation directed to the latency promoter in the present claims is inherent

to the nucleic acid of Nicholas et al. because the promoter sequence disclosed thereby is the same as the promoter sequence claimed. For the reasons discussed above, in particular, Nicholas et al. does not disclose the **specific** nucleic acid sequence of SEQ ID NO:1.

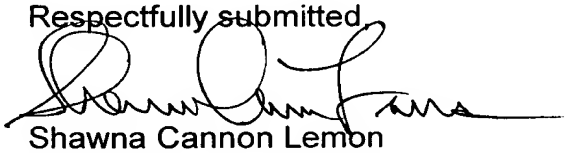
Accordingly, Applicants respectfully submit that Claims 1-3, 4, 7 and 28-30 are not anticipated under 35 U.S.C. § 102 by Nicholas et al., and respectfully request that the rejection of these claims be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

In the event that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully submitted,



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Susan E. Freedman
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